# PQ Performance Qualification - Page 1/13

Biostorage you can depend on

Customer:	Location of installation:	
 Model: SN:	Item number: (manual)	
The PQ consists of inspections of the correct operation of the cabinet under predefined conditions and procedures. Prerequisites for the PQ are IQ (Installation Qualification) and OQ (Operation Qualification), these must be concluded success- fully prior to the initiation of the PQ. This PQ is intended for the following product series: <b>BioCompact, BioCompact II, BioPlus, BioMidi</b>	Person responsible for the cabinet:         Name:         Date:         Signature:         Person responsible for test:         Name:         Date:         Date:         Company:	
Revision 19/02/2019_002	Signature:   Person responsible for verification of test:   Name:   Date:   Date:   Company:   Signature:   Test duration:   Initation (date/time):   Conlusion (date/time):	
$\wedge$ bioline	Model: SN:	

# PQ Performance Qualification - Page 2/13

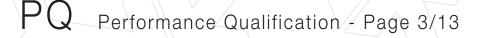
Biostorage you can depend on

Date	Name	Company	Signature	

Model:\_\_\_\_\_

SN: \_\_\_\_\_

 $\wedge$  bioline



bioline

Biostorage you can depend on

Deviations from the specifications dictated in the PQ, are to be reported in the deviation report. The PQ is concluded if all criteria of acceptance are approved and the possible deviations are rectified or accepted.

Meas	urement	- Prerequisites				
ID	DESCRIPTIO	NC			ACCE YES	PTED
P-1		et must be empty while cor awers, shelves etc. ::	nducting tests, ie witho	ut interior fittings		
P-2	The measu Attachment Notes:	irements must be conduct	ed in accordance to IE	C 60068-3-5.		
P-3		ning of the sensors in the d	cabinet must be docur	nented with a		
Cor	nducted by:	Name:	Signature:	Approved (Yes / No):	Date:	
Inspected /	verified by:	Model:		 SN:		

Performance Qualification - Page 4/13

Deviations from the specifications dictated in the PQ, are to be reported in the deviation report. The PQ is concluded if all criteria of acceptance are approved and the possible deviations are rectified or accepted.

Measurement - Prerequisites						
ID	DESCRIPTION		ACCE	PTED		
			YES	NO		
P-4	Measurements made during the PQ tests must attached to the PQ. Attachment: Notes:	be documented and				
P-5	Specify setpoint temperature: °C					
	Specify the ambient temperature: °C					
	Attachment:					
	Notes:					
P-6	Allowed tolerances - Select the tolerance, accord Find model-specific tolerances in appendix.	ing to the model being tested.				
	Tolerance: +/ K					
	Attachment:					
	Notes:					
	Name: Signat	ure: Approved (Yes / No):	Date:			
Cor	nducted by:					
Inspected /	nspected / verified by:					

Model:

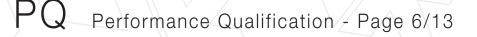
bioline

SN:



Deviations from the specifications dictated in the PQ, are to be reported in the deviation report. The PQ is concluded if all criteria of acceptance are approved and the possible deviations are rectified or accepted.

Meas	urement	- Temperati	ure stab	oilization			
ID	DESCRIPTI	ON				ACCE YES	PTED NO
P-7	the cabine The tempe working sp When the s setpoint te Duration: _	t during normal op erature inside the ca bace have reached system is stable, d mperature and am urements througho ne PQ.	eration. abinet must and mainta ocument or bient tempe	be stabilized - wh ined the same tem	f the cabinet at the P-5.		
	Are the me Attachment Notes: nducted by: verified by:			d tolerances specif Signature:	ied in P-6 ? Approved (Yes / No):	Date:	
) ∧ r	pioline		Model:		SN:		



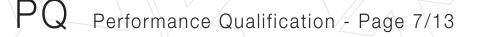
Deviations from the specifications dictated in the PQ, are to be reported in the deviation report. The PQ is concluded if all criteria of acceptance are approved and the possible deviations are rectified or accepted.

Measurement - Door opening test						
ID	DESCRIPTIC	DN			ACCE YES	PTED
P-9	inside the c The temper the working setpoint ter When the s	abinet subsequently aff rature inside the cabine g space have reached a mperature is specified ir system is stable, open the rements, throughout the ed the PQ.	t must be stabilized - where and maintained the same te	e all the points in mperature, the nds.		
P-10		, been achieved within	cified in P-5, measured in th the set time-frame specified			
Cor	nducted by:	Name:	Signature:	Approved (Yes / No):	Date:	
Inspected /	spected / verified by:					

Model:

bioline

SN:



Deviations from the specifications dictated in the PQ, are to be reported in the deviation report. The PQ is concluded if all criteria of acceptance are approved and the possible deviations are rectified or accepted.

Meas	urement	: - Pull-dow	n				
ID	DESCRIPTIO	ON				ACCE	
P-11	<ul> <li>The test is intended to provide substantiation for the time it takes for the inside of the cabinet to reach the setpoint temperature specified in P-5. The initial temperature in the working space is the ambient temperature specified in P-5. The temperature inside the cabinet must be stabilized in all points of the working space.</li> <li>When the system is stable. Turn on the power to the cabinet.</li> <li>The measurements, throughout the pull-down test, must be documented and attached the PQ.</li> <li>Duration:</li> <li>Attachment:</li> <li>Notes:</li> </ul>					YES	NO
P-12	<ul> <li>The time it takes the inside of the cabinet to achieve the setpoint temperature measured in the absolute centre, must not exceed the time-frame specified in the appendix.</li> <li>Have the criteria been met?</li> <li>Attachment:</li> <li>Notes:</li> </ul>						
	nducted by: <sup>/</sup> verified by:			Signature:	Approved (Yes / No):	Date:	
) _ r	pioline				SN:		

Performance Qualification - Page 8/13

Deviations from the specifications dictated in the PQ, are to be reported in the deviation report. The PQ is concluded if all criteria of acceptance are approved and the possible deviations are rectified or accepted.

Measurement - Hold-over						
ID	DESCRIPTIO	ON			ACCE	PTED
					YES	NO
P-13	inside the c Ambient te The temper working sp the tolerand When the s	abinet to reach the en mperature and setpo rature inside the cabin ace have reached an ces are specified in P system is stable, turn rements, throughout ne PQ.	ubstantiation for the time it takes and temperature specified in the a int temperature is specified in F net must be stabilized - where d maintained the same temper -6. off the power to the cabinet. the hold-over test, must be do	appendix. D-5. all the points in the rature throughout,		
P-14	must at lea	st be the time specifie	he cabinet to reach the end ter ed in the appendix.	nperature,		
Name: Signature: Approved (Yes / No): Date Conducted by:						

Model:

bioline

SN:

## PQ Performance Qualification - Page 9/13

Biostorage you can depend on

#### **Deviation Report**

Deviations to the criteria of acceptance are to be documented in the deviation report. A separate deviation report shall be made for each deviation. Mark the entry with the relevant "P-ID" specified in the left column in the test specifications.

P-ID: \_\_\_\_\_

Description of deviation:

Extent to which the deviation has been alleviated:

Additional notes:

Person responsible for test:	Person responsible for verification of test:
Name:	Name:
Date:	Date:
Company:	Company:
Signature:	Signature:
Model:	SN:

# PQ Performance Qualification - Page 10/13

Biostorage you can depend on

Approval of test results - Per	formance Qualification (PQ)
	ualification - PQ were completed with <u>positive</u> results
	ualification - PQ were completed with <u>negative</u> results
ID of steps with negative results:	
Additional notes:	
Person responsible for test	Person responsible for verification of test
Stamp & Signature	Stamp & Signature
 Tel.	Tel.
 E-mail	E-mail
Location & Date	Location & Date
	Model: SN:
$\wedge$ bioline	

PQ	Performance Qualification - Page 11/13	Biostorage you can depend on
/		
NOTES:		
Λ	Model:	SN:
	ioline	

## Q Performance Qualification - Page 12/13

Biostorage you can depend on

### Appendix:

Ρ

	Model	Tolerances	Door opening - recovery time	Pull-down	Hold-over range*	Hold-over
	BioCompact/BioCompact II					
	210 (Solid door)		5 Minutes	25 Minutes		55 Minutes
	210 (Glass door)		6 Minutes	35 Minutes		30 Minutes
	310 (Solid door)		5 Minutes	25 Minutes		55 Minutes
RR	310 (Glass door)	+/- 3K	6 Minutes	30 Minutes	5°C → 10°C	32 Minutes
	410 (Solid door)		6 Minutes	28 Minutes	0 0 7 10 0	62 Minutes
	410 (Glass door)		7 Minutes	35 Minutes		35 Minutes
	610 (Solid door)		3 Minutes	20 Minutes		66 Minutes
	610 (Glass door)		3 Minutes	25 Minutes		40 Minutes
	BioMidi					
	425 (Solid door)		3 Minutes	20 Minutes	5°C → 10°C	63 Minutes
	425 (Glass door)	+/- 3K	4 Minutes	25 Minutes		37 Minutes
	625 (Solid door)		3 Minutes	20 Minutes		63 Minutes
	625 (Glass door)		4 Minutes	25 Minutes		37 Minutes
	BioPlus					
	500 (Solid door)		3 Minutes	22 Minutes		72 Minutes
	500 (Glass door)		4 Minutes	28 Minutes		42 Minutes
	600D / 600W (Solid door)		3 Minutes	20 Minutes		70 Minutes
	600D / 600W (Glass door)		4 Minutes	25 Minutes		41 Minutes
ER	660D / 660W (Solid door)	+/- 2K	3 Minutes	20 Minutes	5°C → 10°C	70 Minutes
	660D / 660W (Glass door)		4 Minutes	25 Minutes		41 Minutes
	930 (Solid door)		5 Minutes	22 Minutes		65 Minutes
	1270 / 1400 (Solid door)		5 Minutes	23 Minutes		78 Minutes
	1270 / 1400 (Glass door)		7 Minutes	29 Minutes		45 Minutes

\* The temperature span between the initial temperature and the end temperature in the hold-over test P-13,14

Note:

<u>RR/ER</u> : Ambient temperature Setpoint temperature						
	Name:		Signature:		oroved s / No):	Date:
Conducted by:					,	
Inspected / verified by:						
		Model:		SN:		
∧	~					

## PQ Performance Qualification - Page 13/13

Biostorage you can depend on

### Appendix:

	Model	Tolerances	Door opening - recovery time	Pull-down	Hold-over range*	Hold-over
	BioCompact/BioCompact II					
RF	210	**	**	60 Minutes		48 Minutes
	310	**	**	60 Minutes	-20°C → -10°C	50 Minutes
	410	**	**	62 Minutes	-20 C → -10 C	52 Minutes
	610	+/- 5K	8 Minutes	55 Minutes		55 Minutes
	BioMidi					
	425		9 Minutes	45 Minutes	-20°C → -10°C	55 Minutes
	625	+/- 5K	8 Minutes	42 Minutes		55 Minutes
	BioPlus					
	500		7 Minutes	45 Minutes		55 Minutes
	600D / 600W		7 Minutes	42 Minutes	-20°C → -10°C	55 Minutes
	660D / 660W	+/- 5K	7 Minutes	42 Minutes		55 Minutes
	930		-	76 Minutes		63 Minutes
	1270 / 1400		10 Minutes	45 Minutes		58 Minutes
	BioMidi					
EF	425	+/- 9K	40 Minutes	107 Minutes	-40°C → -10°C	108 Minutes
	BioPlus					
	600W / 660W	+/- 10K	30 Minutes	57 Minutes	-35°C → -10°C	170 Minutes

\* The temperature span between the initial temperature and the end temperature in the hold-over test P-13,14. \*\* Please contact your local distributor for current information.

Note:

### <u>RF:</u> Ambient temperature +25°C Setpoint temperature -20°C <u>EF (425):</u> Ambient temperature +25°C Setpoint temperature -40°C

<u>EF (600W/660W):</u> Ambient temperature	e +25°C				
Setpoint temperature	e -35°C				
	Name:		Signature:	Approved (Yes / No):	Date:
Conducted by:					
Inspected / verified by:					
<u>^</u>		Model:		SN:	
\ ∧ bioline	<u>^</u>				